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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 09/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/003,481

Applicant(s)

VELLINGER ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Information Disclosure Statement*

1. The information disclosure statement filed 07 May 2002 has been considered and made of record.

### *Specification*

2. The abstract of the disclosure is objected to because it is too long. Correction is required. See MPEP § 608.01(b).
3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the **range of 50 to 150 words**. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is indefinite because it includes numerous occurrences of listings of structural elements and fails to positively set forth structural cooperation between the listed elements. First the recited reactor vessel is recited to include a cylindrical wall, two cover plates, two rotary unions, fill ports and a polymer filter, however, the claim fails to set forth how these elements cooperate with one another to form the claimed vessel. For example, how does the recited filter cooperate with the rest of the vessel? Is it interior to the cylinder or provided on a port or union? The same holds true for the other recited elements that make up the claimed apparatus in addition to the recited vessel. Finally, while the claim recites a sealed external housing, it is not clear if the recited power supply and computer are part of the claimed device since they have not be positively recited as elements of the apparatus. The current claim language merely states that the housing is for all components except power supply and computer. Also, "said cylindrical vessel" lacks antecedent basis.

With respect to claim 2, mere recitation of "a rotary multiple sample collector" linked with its intended use is not enough to clearly define the metes and bounds of the structure of the device encompassed by this claim language. Note, this claim language is not considered to be covered by 35 USC 112, sixth paragraph.

Claim 3 is indefinite for the same reasons as set forth with respect to claim 2. It is not clear how the recited means cooperate with the physical structure of the recited rotating inlet and compartment with a filter. Clarification and/or correction is requested.

***Claim Rejections - 35 USC § 103***

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knazek et al. (WO 90/02171) in view of Goffe (US 5,882,918), Kearney (US 5,424,209) and Pickering (US 4,161,172).

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The reference of Knazek et al. discloses a bioreactor apparatus that includes a cylindrical reactor vessel (11) that includes two cover plates, fill ports (13a, 13b, 15a, 15b) and a polymeric filter (12) (See page 21, lines 4-14). The apparatus includes a length of permeable tubing (18) and a pump (24), a fresh medium storage container (150), a sample collection container (160) that includes pinch valves (See page 13, lines 6-20). The device when used in an incubator device includes a device for controlling humidity (See page 18, lines 19-28) and is sealed within the external housing of the incubator device. The apparatus also includes a controller (80) located outside the incubator enclosure (See page 19, lines 28-34).

The above claim first differs by reciting that the reactor vessel includes rotary unions.

The reference of Goffe discloses that it is known in the art to rotate a hollow fiber reaction vessel that is held within an incubation enclosure by rotating the vessel (See column 5, lines 15-49).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to rotate the vessel of the primary reference so as to agitate the vessel as suggested by the reference of Goffe. When employing complete 360 degree rotation as suggested by Goffe, it would have been obvious to provide the vessel with rotary unions for the known and expected result of allowing the medium to communicate with the vessel during the rotation of the vessel.

With respect to the levels of containment recited in the claim, the reference of Kearney discloses that it is known in the art to provide at least three levels of containment with respect to a self-contained culture system (See the abstract).

As a result, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide levels of containment within the system of the primary reference

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for the known and expected result of isolating the cells and medium from the ambient surroundings.

While the primary reference discusses the use of a humidity control device, the reference is silent as to the structure of the device.

The reference of Pickering discloses that it is known in the art to provide an incubator device with a humidifier that includes a water-saturated sponge (See column 11, lines 47-51).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the incubator of the primary reference with a humidifier as disclosed by the reference of Pickering for the known and expected result of providing a means recognized in the art for stabilizing the humidity within an incubator device.

With respect to the use of peristaltic pumps, while the primary reference is silent as to the use of these pumps, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ peristaltic pumps within the system of the primary reference for the known and expected result of providing an art recognized means for flowing media within a culture system while minimizing the contact of the media with the pumping device.

Note the control of the system of the primary reference is capable of being programmed in view of the use of a microprocessor to control the system (See page 26, lines 14-34).

With respect to the claimed use of a bag rather than a bottle as a container for the medium, the primary reference recognizes that other known culture containers can be used in place of the disclosed bottles (See page 26, lines 27-33). As a result, it would have been obvious

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to one of ordinary skill in the art to employ a bag rather than a bottle for the known and expected result of providing an alternative means recognized in the art to achieve the same result.

***Allowable Subject Matter***

10. Claims 2 and 3 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: Claims 2 and 3 would be allowable because the prior art of record fails to teach or fairly suggest the combination of the elements recited in claim 1 with a sampling system as recited in claims 2 or 3 wherein the sampling system includes a plurality of sample retaining chambers and filters with a rotary inlet port and wherein the sampling system is capable of collecting cells on the filter, fixing the cells and storing the cells.

***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The references of Walker (US 4,618,586) and Harm et al.(US 4,650,766) are cited as prior art references that disclose culture systems that include systems for controlling the media contacted with the culture chamber.



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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006.

The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB